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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,247	08/15/2006	Philippe Chavignac	SAIME 3.3-004	1734
530 7590 09/24/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER MATTER, KRISTIN CLARETTE	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 09/24/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/550,247

**Applicant(s)**

CHALVIGNAC, PHILIPPE

**Examiner**

KRISTEN C. MATTER

**Art Unit**

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Action is in response the amendment filed 7/28/2009. Claims 1, 2, 5-9, 12, and 14 have been amended and no claims have been added or cancelled. Thus, claims 1-16 are currently pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom (US 5,937,853) in view of Chalvignac (US 2002/0014239) and Ernst (US 3,961,627).**

Regarding claim 1, Strom discloses a ventilator capable of operating in inhalation and exhalation phases, the apparatus comprising: an inhalation duct (4) and an exhalation duct (6), a pressure and flow rate sensor (10) associated with the inhalation duct (see Figure 1), and a regulating unit (14) that takes a first reference value input (see Figure 1) and a second input from the pressure and/or flow sensor (see Figure 1) such to allow real time transmission of a pressure or flow signal for determining barometric or volumetric mode operation (see column 4, lines 19-28) and controlling the operation of the gas source (see Figure 1).

Strom is silent as to inhalation and exhalation valves, the inhalation valve being controlled by an automatic control unit separate from a comparator and receiving signals from

the sensors. Strom also does not give details as to the pressurized gas source (16). However, Chalignac discloses a similar ventilator with a pressurized gas source (fan 12), an inhalation valve (16, 54) and an exhalation valve (32), the inhalation valve being controlled by an automatic control unit. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Strom's device with the controller, fan air source and inhalation/exhalation valves as taught by Chalignac in order to deliver a constant flow of air to the patient as needed. Such a modification would involve simple substitution of a well known method for supplying gas into a well known system that would yield predictable results that do not patentably distinguish over the prior art of record. Furthermore, it appears as though the system of Strom would perform equally well with the fan and valve system of Chalignac.

Strom/Chalignac does not explicitly have an automatic control unit separate from the control means noted above. However, absent a critical teaching and/or showing of expected results from a separate controller for the valves and comparator, examiner contends that the number of individual control units is an obvious design consideration to one of ordinary skill in the art at the time the invention was made in order to have back up controls in case one breaks for example. Also, since Strom has a controller that directly controls the gas delivery unit and Chalignac has a controller that directly controls the valves, it would have been obvious to keep the controllers operating as is in the modification and it appears as though the system would work equally well with separate controllers for the comparator and the valves.

Strom further discloses that the ventilator automatically switches between pressure and volume support (column 2, lines 35-40 and 48-65 and column 4, lines 19-28) and that the sensor

signals are compared against threshold values (see for example column 5, lines 45-50) and the result is used to control gas delivery. This implies that Strom has a comparator and a switch. However, to the extent that Strom does not explicitly disclose a comparator, Ernst teaches a selection means (comparator 7) capable of selecting a parameter of flow or pressure to define a gas related parameter (see col. 4, lines 5-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac to include a comparator/selection means as taught by Ernst in order to permit switching between volume and pressure based regulation (see Ernst col. 4, lines 36-44) using a well known method/device. As discussed above, which control unit controls the switch is an obvious design consideration absent a critical teaching and/or a showing of unexpected results. Additionally, Ernst teaches an automatic control unit 8 for controlling the selection means separate from any control of a gas source.

Regarding Claim 2, the inhalation valve of Chalvignac is operable to generate leaks (para. 0061, line 6).

Regarding Claim 3, the gas source of Chalvignac is a centrifugal fan turbine with an axial air intake and peripheral output (para. 0060, lines 1-5). Chalvignac does not disclose the inertia value/moment of inertia of the fan is  $150 \text{ g}\cdot\text{cm}^2$ . However, it would have been obvious at the time the invention was made to modify the inertia value/moment of inertia of the fan to be  $150 \text{ g}\cdot\text{cm}^2$  since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding Claim 14, the structural elements recited are noted above with respect to claim 1. The instant method steps (including selection of volumetric mode and controlling the gas

source) would have been obvious to one of ordinary skill in the art, upon seeing the modified Strom reference, because they would have directly resulted from use of the modified device.

Regarding Claim 15, Chalvignac discloses that no pressure difference exists between the upstream part and the downstream part of the ventilator shown in Figure 1 when the inhalation valve opens. Flow is also permitted through bypass pipe 18, which eliminates pressure differences.

Regarding Claim 16, control of the volume of gas delivered by the modified system is obtained by control of the rotation speed of a rotor of the gas source (para. 0027, lines 1-3 of Chalvignac).

**Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, and Ernst as applied to claim 1 above, further in view of Whitwam (US Patent 5,307,795).**

Regarding Claim 4, Strom as modified by Chalvignac/Ernst does not disclose a second flow sensor on the expiratory duct. However, Whitwam teaches a flow sensor 15 on an expiratory duct (col. 2, line 54, see Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the system of Strom/Chalvignac/Ernst to include a second flow sensor as taught by Whitwam so that the total expired volume from the patient can be measured.

Additionally, Strom/Chalvignac/Ernst does not disclose a comparison means for the flow rate sensors to compare the respective flow rates in the inhalation and exhalation ducts. Whitwam teaches a comparison means 20 (col. 3, lines 5-15) for comparing the respective flow

rates in the inhalation and exhalation ducts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the system of Strom/Chalvignac/Ernst to include a comparison means as taught by Whitwam so that the expired tidal volume can be measured using a well known means (col. 3, line 13).

Regarding Claim 5, Whitman also teaches processing means 23 ( col. 3, line 15) operable to filter a difference between the respective flow rates in real time. The processing means is associated with the comparison means (Fig. 1).

Regarding Claim 6, the combination of Strom/Chalvignac/Ernst and Whitwam will have the processing means connected to the automatic control unit.

The modified Chalvignac system does not disclose a memory connected the processing means. Whitwam discloses a memory 24 connected to a processing means. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac/Ernst to include a memory connected to the processing means as taught by Whitwam so that flow rate measurements can be stored.

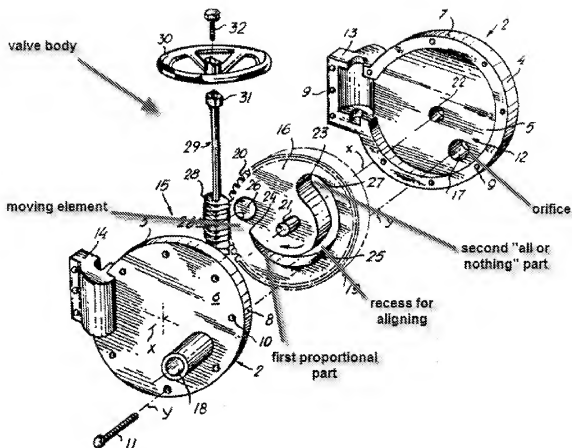
The addition of Whitwam's sensors and comparison means as noted above includes circuitry programmed to trigger a new inhalation phase when the filtered flow rate difference is higher than a pre-determined threshold (col. 1, lines 49-62).

**Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, and Ernst as applied to claim 1 above, further in view of Torres (US Patent 5,308,040).**

Regarding Claim 7, Chalvignac's inhalation valve 16 inherently has an orifice connected to the inhalation duct. This valve is a balloon valve, so it also appears to be operable to block the orifice in a closed position and partially free the orifice in an open position. However, Chalvignac does not disclose the valve comprising a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation. Torres teaches a valve with a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation, as shown below. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Chalvignac's inhalation valve in the modified Strom device with the valve as taught by Torres because both valve structures were well known in the art and substituting one valve for another would work equally well.

The first part of the recess shown below is triangular at the tip. The second part of the recess is not rectangular. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape to be rectangular because a mere change in shape is generally considered to be obvious to one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)





Regarding Claim 8, Torres's valve has the recess shaped so that when the moving element moves from the closed position to the open position, the first part is aligned with the orifice, and the second part is aligned with the orifice if the movement continues (clockwise motion in the figure above).

Regarding claim 9, the base of the triangle of the first part shown above would be parallel to one of the sides of the rectangular end of the recess shown above.

**Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chavignac, and Ernst, as applied to claim 1 above, further in view of Levin (US 5,813,410).** The difference between instant claims 10 and 12 and the modified Strom/Chavignac/Ernst device is a micro-turbine for controlling the exhalation valve. However, Levin discloses that micro-turbines are well known electrical energy generating means for assisting in driving various medical devices (column 3, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a micro-turbine for providing the power needed to control the exhalation valve in the Strom/Chavignac/Ernst device as taught by Levin in order to save energy by using the closed loop system's own flow to produce the power or to include a back-up means from controlling the valve in case of failure of other system components. Such a modification would involve a mere substitution of a well known method of providing power in a well known system that would yield predictable results that do not patentably distinguish over the prior art.

**Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chavignac, Ernst, and Levin as applied to claim 10 above, further in view of DeVries (US Patent 6,102,038).**

Regarding Claim 11, the modified Strom/Chavignac/Ernst/Levin device is silent as to the micro turbine being directly connected to the expiratory valve with no element in between. DeVries teaches a balloon valve 32 (Fig. 1) directly connected to an air source 56 with no element in between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chavignac/Ernst/Levin to have

the fan directly connected to the inhalation valve as taught by DeVries so that the valve can be easily controlled by slowing or accelerating the fan to deflate or inflate the valve. Furthermore, it appears as though the device would work equally well with the turbine being directly attached to the exhalation valve.

**Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, Ernst, and Levin as applied to claim 12 above, further in view of Tobia (US Patent 5,735,267).**

Regarding Claim 13, Chalvignac discloses the gas source/fan operating constantly (para. 0060, line 4) and since flow is constantly flowing through the closed loop system the micro-turbine would also operate constantly.

The modified reference is silent as to the expiratory valve being controlled by selective connection of a pneumatic control line of the expiratory valve with the micro turbine. Tobia teaches an exhalation valve 26 that is a balloon valve (col. 4, line 36) that is controlled by selective control of a pneumatic control line 18 via flow control solenoid valve 16 (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac/Ernst/Levine to include a solenoid controlling flow to the expiratory valve as taught by Tobia so that a controller can precisely control the inflation and deflation of the balloon valve.

***Response to Arguments***

Applicant's arguments, with respect to the rejection(s) under Chavignac and Ernst alone have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Strom.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Du et al, is cited to show another control unit that controls a gas delivery unit based on sensed breathing parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771